



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/882,950	06/26/97	KAUFFMAN	S 2860-27

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HM12/0103

EXAMINER

HOUTTEMAN, S

ART UNIT

PAPER NUMBER

1656

24

DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/882,950

Applicant(s)

Kauffman et al.

Examiner

Scott Houtteman

Group Art Unit

1656



☒ Responsive to communication(s) filed on 10/6 and 10/19/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-50 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10/19/00

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's response, filed 10/6/00, has been carefully considered with the following effect:

The objections and rejections of paragraphs 4A and 4B, Office action mailed 3/29/00, have been withdrawn in view of applicants amendments.

The objections and rejections of paragraphs 5 and 7, Office action mailed 3/29/00, have been maintained.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record. X

Applicant argues that the specification contains numerous guidelines, for example starting materials, reactions, reaction conditions. This disclosure allegedly provides the proper enablement.

This argument is not persuasive. An example of the starting materials is found in the specification on page 9, line 19-20. "Substrates for the processes described herein include all organic compounds." This sort of generic, broad guidance provides very little in terms of practical guidance.

There is not guidance, for example as to how to generically perform applicants "sib selection" process to provide "ready winnowing." In order to carry out this process one must be able to divide the population in to two halves. At this point, the "desired" product would be in a vanishingly small population and any "signal" would likely be drowned out by the vast majority of background signals from the exogenous products. Thus, this procedure is practically limited to "desired" products with huge signals which are easy to detect.

Furthermore, even if there is a signal is detectable, are more problems to be overcome. The "sib selection" requires one to select one "sib" that contains the desired activity and produce more of this half of the population. This is possible in only a single type of population. A library of gene products cloned in a population of bacteria. There is no guidance on how one could replicate any other type of library.

It is important to note that these claims are nowhere limited to merely genetic libraries. These claims read on the production of any molecule, any chemotherapy drug, any drug molecule with any pharmacological activity whether it dulls pain, lowers blood pressure, cures cancer or restores hair loss. All of these molecules could be made by the claimed methods and thus are within the scope of these claims.

Applicant argues that it is only necessary to "characterize" the desired product. This argument is not persuasive. In order to "characterize" the desired product, the product must be uniquely identified. In many ways, this process is even harder than the one outlined above. Above the "desired" products gave off a signal. Isolating the source of a strong signal requires that one merely follow the signal through purification procedures. In the later case,

“characterization,” one would be required to de extensive assays to isolate a set of characteristics within a complex mixtures. One would have no way to determine which of the components of the mix is providing which set of characteristic properties.

4. Claims 1-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al., Trends Biochem., 12(1):19-26, 1/1994 (Jacobs) for reasons of record.

Applicant argues that Jacobs is post publication. The rejection dealt with this issue. Applicant did not address this portion of the rejection. Briefly, the law states that the prior art is the grounds of the rejection. In this case, the article is a review article of the prior art. Thus, the publication of Jacobs is not relevant. What is relevant is the publication date of the prior art which Jacobs reviews. Applicant does not dispute that any of the prior art pointed out in Jacobs arose post filing. Furthermore, applicant has not distinguished the claims from the prior art taught in Jacobs. Presumably, applicant is conceding that the claims read on the features pointed out in Jacobs.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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6. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 8:30 AM - 3:30 PM. The examiner can also be reached on alternate Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
January 2, 2001

A handwritten signature in black ink, appearing to read "Scott W. Houtteman". The signature is fluid and cursive, with the first name "Scott" being more prominent than the last name "Houtteman".

**SCOTT W. HOUTTEMAN
PRIMARY EXAMINER**